November 25, 2020

MIT Global Co., Ltd.
Lim Won
Regulatory Affairs Manager
474 Dunchon-daero, Jungwon-gu
Seongnam-si, Gyeonggido 13229
SOUTH KOREA

Re: K202269
Trade/Device Name: PRE-MILLED Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: October 15, 2020
Received: October 26, 2020

Dear Lim Won:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew Steen
Assistant Director
DHT1B: Division of Dental Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202269

Device Name
PRE-MILLED Abutment

Indications for Use *(Describe)*
The PRE-MILLED Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

It is compatible with the following systems:
• Zimmer 3.1mmD Dental Implant System (K142082)
• Screw Vent® and Tapered Screw Vent® (K013227)

All digitally designed abutments for use with the PRE-MILLED Abutments must be designed and milled through the 3Shape CAD/CAM System and are intended to be sent to a validated milling center for manufacture.

The PRE-MILLED Abutment is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System (K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

K202269

Applicant

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Phone:	+82 31 745 2838
Contact:	Lim, Rokwon
Email:	Email: rokwonlim@mit-global.com

Date Prepared: 11/20/2020

Subject Device

Trade Name:	PRE-MILLED Abutment
Common Name:	Endosseous dental implant abutment
Classification Name	Abutment, Implant, Dental, Endosseous
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Primary Predicate

Trade Name:	Medentika CAD/CAM Abutment (K150203)
Common Name:	Endosseous dental implant abutment
Classification Name	Abutment, Implant, Dental, Endosseous
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Reference Device

Trade Name:	Zimmer 3.1mmD Dental Implant System (K142082)
Common Name:	Endosseous dental implant abutment
Classification Name	Abutment, Implant, Dental, Endosseous
Product Code:	NHA
Panel:	Dental
Regulation Number:	21 CFR 872.3630
Device Class:	Class II

Reference Device

Trade Name:	Screw Vent® and Tapered Screw Vent® (K013227)
	Endosseous dental implant abutment
Common Name:	Abutment, Implant, Dental, Endosseous
Classification Name	NHA
Product Code:	Dental
Panel:	21 CFR 872.3630
Regulation Number:	Class II
Device Class:	

Device Description

The PRE-MILLED Abutment is used in fabricating a patient-specific abutment in titanium alloy. It has a pre-manufactured connection interface that fits directly to an endosseous dental implant. It is made of Titanium grade Ti-6A1-4V ELI (meets ASTM Standard F-136).

The abutment is placed over the implant shoulder and mounted into the implant with the provided screw. The design and manufacturing of the patient-specific abutments take into consideration the shape of the final prosthesis based on the patient's intra-oral indications using CAD/CAM system.

Mechanical resistance of the implant-abutment connection is essential to ensure the correct long-term functional performance of the complete dental restoration. Dimensional compatibility and mechanical performance of abutments and screws together with the underlying implant are of primary importance. These concepts are the basis upon which the system design characteristics and functional performance are established.

The PRE-MILLED is a device that can only be sold, distributed, or used upon the order of an authorized healthcare provider, generally referred to as prescription (Rx) devices.

The proposed abutments are available in internal connection, and are compatible with Zimmer 3.1mmD Dental Implant System (K142082) and Screw Vent® and Tapered Screw Vent® (K013227).

The PRE-MILLED Abutments are compatible with the following OEM devices:

No.	Implant System	Diameters (Ø)	Implant Platform (mm)	Type of Implant-Abutment Connection
1	Zimmer 3.1mmD Implant	3.1	2.9	Internal Hex Conical Connection
2	Zimmer SV/TSV	3.7	3.5	
3	Zimmer SV/TSV	4.1	3.5	
4	Zimmer SV/TSV	4.7	4.5	
5	Zimmer SV/TSV	6.0	5.7	

Indication for Use

The PRE-MILLED Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

It is compatible with the following systems:

- Zimmer 3.1mmD Dental Implant System (K142082)
- Screw Vent® and Tapered Screw Vent® (K013227)

All digitally designed abutments for use with the PRE-MILLED Abutments must be designed and milled through the 3Shape CAD/CAM System and are intended to be sent to a validated milling center for manufacture.

The PRE-MILLED Abutment is compatible with the following devices:

Zimmer 3.1mmD Dental Implant System (K142082)
Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex

Screw Vent® and Tapered Screw Vent® (K013227)
Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex
Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex
Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex

Summary of Technological Characteristics

The subject device, the primary predicate have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the primary predicate listed above.

Non-clinical Testing

The subject device was tested to evaluate its substantial equivalence according to the following standards.

- Fatigue Test according to ISO 14801:2016
- End User Steam Sterilization Test according to ISO 17665-1:2006, 17665-2:2009 and ANSI/AAMI ST79:2010.
- Biocompatibility tests according to ISO 10993-1:2009, ISO 10993-5:2009, and ISO 10993-10:2010.

Non-clinical test data was used to evaluate the proposed device's substantial equivalence compared to the primary predicate. The results of the above tests have met the criteria of the standard and demonstrated the substantial equivalence with the primary predicate.

Non-clinical testing was conducted in accordance with FDA Guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments", and it consisted of testing finished assembled implant/abutment systems of the worst-case scenario through fatigue testing.

Dimensional analysis and reverse engineering of the implant-to-abutment connection platform were performed, including an assessment of maximum and minimum dimensions of critical design aspects, tolerances, and cross-sectional images of the submission device and compatible implant body as well as the OEM implant body, the OEM implant abutment, and the OEM abutment screw. The testing aided implant to abutment compatibility and has established substantial equivalency of the proposed device with reference devices.
Clinical testing was not necessary to establish substantial equivalency of the device.

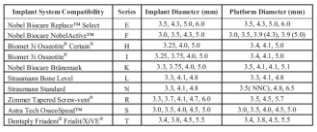
Primary Predicate / Reference devices:

The subject device is substantially equivalent to the following primary predicate and reference devices:

- Primary Predicate
  - Medentika CAD/CAM Abutment (K150203)

- Reference devices
  - Zimmer 3.1mmD Dental Implant System (K142082)
  - Screw Vent® and Tapered Screw Vent® (K013227)

Comparison between Primary predicate

Feature	Proposed Device PRE-MILLED Abutment	Primary predicate Medentika CAD/CAM Abutment	SE discussion
Applicant	MIT Global Co., Ltd.	Medentika GmbH	-
Trade Name	PRE-MILLED Abutment	Medentika CAD/CAM Abutment	-
510(K) No.	K202269	K150203	-
Classification Name	Endosseous Dental Implant Abutments (872.3630)	Endosseous Dental Implant Abutments (872.3630)	Identical
Product Code	NHA	NHA	Identical
Screw and Abutment Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Indications For Use	The PRE-MILLED Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. It is compatible with the following systems: • Zimmer 3.1mmD Dental Implant System (K142082) • Screw Vent® and Tapered Screw Vent® (K013227) All digitally designed abutments for use with the PRE-MILLED Abutments must be designed and milled through the 3Shape CAD/CAM System and are intended to be sent to a validated milling center for manufacture. The PRE-MILLED Abutment is compatible with the following devices:	(Medentika TiBase CAD/CAM Abutments not applicable to this submission) Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.  Medentika Preface is intended for use with the Straumann CARES System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann CARES validated milling center.	The subject device is substantially equivalent in indications and design principles to the primary predicate device listed above. Provided tables are comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device. The Indications for Use Statement (IFUS) for the subject device is substantially equivalent in intended use to the primary predicate device. All are intended for use with endosseous dental implants in the maxilla and mandible to provide functional and esthetic rehabilitation of the edentulous maxilla and mandible. Slight differences in the language of the subject device and primary predicate is Indications for Use statements do not affect the intended use as an endosseous dental implant abutment for support of a prosthesis to restore chewing function. The minor differences between the subject device and the primary predicate device are related

Feature	Proposed Device PRE-MILLED Abutment	Primary predicate Medentika CAD/CAM Abutment	SE discussion
	Zimmer 3.1mmD Dental Implant System (K142082) Implant Body Diameter 3.1/ Implant Platform Diameter 2.9 / Internal Hex Screw Vent® and Tapered Screw Vent® (K013227) Implant Body Diameter 3.7/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.1/ Implant Platform Diameter 3.5 / Internal Hex Implant Body Diameter 4.7/ Implant Platform Diameter 4.5 / Internal Hex Implant Body Diameter 6.0/ Implant Platform Diameter 5.7 / Internal Hex		to the compatible OEM implant lines and the implant platform diameter.
Platform Diameters	2.9/3.5/4.5/5.7mm	3.0 - 7.0	The difference between the two products in the platform diameter are the same except for the minimum diameter. The minimum diameter of the product compatible with the subject device is smaller than the primary predicate device (K150203). Since the platform diameter of the subject device is included in the range of primary predicate's diameter, therefore, it doesn't impact the product's substantial equivalence.
CAD Design Limits	Maximum Angulation : 0~25° Maximum Cuff Height : 0.5~5mm Minimum Diameter : Ø 4.0~ Ø 8.0mm Minimum Wall Thickness : 0.4mm Minimum Post Height : 4mm	Maximum Angulation : 0~30° Maximum Cuff Height : Not identified Minimum Diameter : Ø3.0~ Ø7.0mm Minimum Wall Thickness : Not identified Minimum Post Height : Not identified	The minor difference between the two products in the design parameters are the minimum maximum diameter and angulation. The minimum diameter of the product compatible with the subject device is larger than the primary predicate device. The diameter of the primary predicate device is Ø3.0mm~ Ø7.0mm, while the subject device can be designed from Ø 4.0mm up to Ø8.0mm. The maximum angle of the product compatible with the subject device is smaller than the primary predicate device. The angle of the primary predicate device is 30°, while the subject device can be designed up to 25°.

Feature	Proposed Device PRE-MILLED Abutment	Primary predicate Medentika CAD/CAM Abutment	SE discussion
Surface Treatment	None	None	-
Sterile	Non-sterile	Non-sterile	-

Substantial Equivalence Discussion

PRE-MILLED Abutment incorporates the same material, indications for use, dimension, design, abutment seat, screw seat, anatomical site, connection, type of retention and technological characteristics as the primary predicate.

The Indications for Use of the subject and primary predicate are identical other than the compatible implant bodies. This difference is mitigated by fatigue testing, reverse engineering, dimensional analysis, and identification of reference predicate for compatible implant bodies. Both the predicate and subject devices are intended to be milled into patient-specific abutments using CAD/CAM technology under the manufacturing control of the sponsor.

Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicate and do not raise different questions of safety and effectiveness than the predicate.

PRE-MILLED Abutments are compatible with reference devices (K142082 and K013227). Each PRE-MILLED abutment platform has a precision implant/abutment interface corresponding to the implant system predicate for that platform.

Conclusion

The PRE-MILLED Abutment constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. This system has the same intended use and fundamental scientific technology as its primary predicate. Therefore, PRE-MILLED Abutment and its predicate are substantially equivalent.